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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,761	03/10/2005	Alan Crossman	0206.MO.04	3221

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
10/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efspatents@sbiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/527,761	CROSSMAN ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,15 and 27-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15 and 27-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/27/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 26, 2010 has been entered.

This Office Action is in response to applicant's arguments filed on May 26, 2010. Claim(s) 14-15 and 27-35 are pending and examined herein.

Response to Arguments

Applicant's arguments with respect to the 103(a) rejection of claims 14-15, 19, and 25-27 as being unpatentable over Chenard (EP 0900568 A2) in view of Skradski (*Epilepsia*, 2000) in further view of Dursun et al. (*Canadian Journal of Psychiatry*, 2000) have been fully considered.

Applicant argues that Chenard discloses a large number of compounds as being suitable AMPA receptor antagonists but fails to teach or suggest the use of compound I as an agent for treating dyskinesia (chorea or dystonia).

Examiner respectfully notes that Chenard was employed to demonstrate that it is known in the art to employ AMPA receptor antagonists to treat dyskinesia. Examiner

employs Skradski to demonstrate that topiramate is also an AMPA receptor antagonist and can be among the choice of compounds used to treat dyskinesia.

Applicant argues that Skradski does not teach that topiramate is an AMPA receptor antagonist. Applicant further purports this position through an Affidavit submitted by Dr. Erwan Bezard on September 16, 2010. Upon consideration of the arguments and Dr. Bezard's affidavit with regard to the Skardski reference, said reference is hereby withdrawn from the rejection statement.

Examiner respectfully notes that although arguments refuting the Skradski reference are withdrawn, it is still the opinion of the Examiner that topiramate was known to have AMPA antagonist properties at the time of filing of the instant invention. Based on a comprehensive search performed on topiramate and its property as an AMPA receptor antagonist, there is much literature (at the time of filing) that would lead one of ordinary skill in the art to have known that the instant compound possesses such properties. As a result, although the 103(a) rejection of the previous Office action is withdrawn because of the Skradski reference, a new rejection is set forth on record introducing an alternate reference that specifically states that topiramate is an APMA receptor antagonist.

A new 103(a) rejection is made of record in the Office action below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-15 and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenard (EP 0900568 A2) of record in view of Zullino (Progress in Neuro-Psychopharmacology and Biological Psychiatry, 2002) in further view of Dursun et al. (*Canadian Journal of Psychiatry*, 2000) of record.

Chenard teaches the administration of AMPA receptor antagonists for the treatment of dyskinesia which results as a side effect of dopamine agonist therapy given as a therapeutic regimen for Parkinson's disease (page 2, lines 5-7).

Chenard teaches that after a period of chronic administration of dopamine agonist therapy to treat Parkinson's disease motor abnormalities such as choreatic dyskinesia and dystonia arise (page 2, lines 21-25).

Chenard teaches that the term dyskinesia means any abnormal or uncontrollable movement including **chorea**, tremor, **dystonia**, myoclonus and tic, among others (page 10, lines 50-51).

Chenard teaches dopamine agonist therapies include the administration of one or more of the following: L-dopa, bromocriptine, pergolide, ropinirole, cabergoline, and lisuride (page 10-11, [0014]).

Chenard does not teach topiramate as the AMPA receptor antagonist.

Zullino teaches that topiramate is an AMPA receptor antagonist (abstract; discussion).

Dursun discloses a study whereby a 29-year-old male diagnosed with chronic paranoid schizophrenia is treated with clozapine and responds positively to the medication. The patient however develops some side effects including myoclonic jerks in both hands, arms, and shoulders, in addition to excessive weight gain (column 1, paragraph 1). The same patient is then administered topiramate which showed

improvement in his mood and complete improvement of his myoclonic jerks (column, paragraph 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed an AMPA receptor antagonist as a treatment for dyskinesia as taught by Chenard and also employed topiramate. The motivation, provided by Zullino, teaches that topiramate is an AMPA receptor antagonist. Thus one would expect with a reasonable degree of success that the treatment of dyskinesia with one AMPA receptor agonist over another would be equally successful, in the absence of unexpected results. Additionally, one would be further encouraged that the employment of topiramate in the treatment of dyskinesia would be successful in light of the teachings of Dursun. As discussed above, Dursun teaches that topiramate is able to improve myoclonic jerks in the patient (which also arises as a side effect of a drug). As set forth on record, Chenard teaches that myoclonus is also encompassed by dyskinesia. Thus as one of ordinary skill in the art would expect with a reasonable degree of success that topiramate would be able to treat the abnormal or uncontrollable movements associated with dyskinesia.

Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenard (EP 0900568 A2) of record in view of Zullino (Progress in Neuro-Psychopharmacology and Biological Psychiatry, 2002) in further view of Dursun et al. (*Canadian Journal of Psychiatry*, 2000) of record as applied to claims 14-15 and 27-33 above in further view of Crossman (Movement Disorder, 1990).

Chenard, Zullino, Dursun are discussed above. Chenard teaches a number of dopamine agonists that may exacerbate or may accompany the dyskinesia.

Chenard does not specifically teach the dyskinesia as being associated apomorphine treatment.

Crossman teaches dyskinesia can occur during treatment with not only levodopa but also direct-acting dopamine agonists such as apomorphine, pergolide, bromocriptine (page 100, column 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have administered topiramate for the treatment of dyskinesia as discussed above arising from dopamine agonist therapy as taught by Chenard as well as the dopamine agonist apomorphine. The motivation, provided by Crossman, teaches that dopamine agonists such apomorphine in addition to pergolide, bromocriptine can result in dyskinesia. Thus it would have been obvious to the skilled artisan that apomorphine is among the several dopamine agonists that can results in dyskinesia.

Based on the foregoing reasons, the instant claims are deemed unpatentable over the cited art.

Conclusion

Claims 14-15 and 27-35 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627